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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/432,881	MARKEY ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,14-26,32-34,47-55 and 97-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-9,14-26,32-34,47-55 and 97-151* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims:

Claims 1-9, 14-26, 32-34 47-55, and 97-151 are pending in this application.

Claims 1-9, 14-26, 32-34 47-55, and 97-151 have been amended.

Claims 1-9, 14-26, 32-34 47-55, and 97-151 are been examined.

Claims 1-9, 14-26, 32-34 47-55, and 97-151 are rejected.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12 October 2004 has been considered.

Response to Restriction filed 10/12/04: Claims 1-9, 14-26, 32-34 47-55, and 97-151 remain under consideration.

A Response to a Restriction Requirement filed May 20, 2004 is acknowledged. Claims1-9, 14-26, 32-34 47-55, and 97-151 are elected, with examining claim 50 intact.

Applicant's election with traverse of Claims1-9, 14-26, 32-34 47-55, and 97-151 in the reply filed on October 12 is acknowledged. The traversal is on the ground(s) that all the materials noted in claim 50 are patentably distinct form one another. In view of the traverse all pending claims are rejoined and the species election is vacated.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by MacKenizie et al., Fundamental and Applied toxicology.

MacKenzie et al., disclose reduction of body weight/mass in individuals receiving the instant active agents (alkali and alkaline earth metal docusates) in claims 1 and 14-18. (See abstract). The reference teaches a wax like solid that is used as a wetting agent in a variety of industrial and pharmaceutical food additive (see page 53) and also (page 54 where the (dioctyl sulfoccinate (DSS) is used polymeric coating) which is equivalent to a solid matrix, which anticipates the claim since the specification (see pages 6-7) there has no definition of a solid matrix. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

The instant claims 1, and 14-18 require administration of specific levels of active ingredient (see page 54 left column second ¶ underlined section, and also at page 54 right hand col. under diet preparation underlined). MacKenize discloses the active agent is present at 0.1, 0.5 or 1.0 %, calculated to be 1000 mg as the purity of the active metal docusate is 99.4% (see section Methods) which meets the limitation(s).

II. Claims 49-55 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/47285 ('285).

The '285 reference discloses a pharmaceutical composition consisting of cellulose polymers (current claim 49) (see page 4 lines 7-10), hydroxyethylcellulose, carboxymethyl cellulose, hydroxypropylcellulose, polyethylene oxide as in current claims 50-51 and 55 (see page 4 lines 25+, and page 5 lines 1-5) as directed to instant claims 1-9, 14-26, 32-34 47-55, and 97-151.

With regard to claims 52-54, the fed mode-inducing agent is contained in a solid coating (see page 5 lines 15-20) in a water-soluble matrix.

III. Claims 1 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kais et al., US Patent 5,516,524 ('524).

The '524 patent discloses methods of treating constipation in human subjects by administering to said human a laxative composition (drug) dioctyl sulfoccinate (DSS) (fed mode agent) and the solid matrix-a bulk fibre methylcellulose (see abstract, and also col. 7 lines 5-10), i.e., the solid matrix and therefore anticipates the claim, since the specification (see pages 6-7) there is no definition of a solid matrix. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

The reference also discloses a dose of about 200 mg to 300 mg of sodium or calcium docusate (see abstract, col. 9-11,col. 13, lines 34-45. col. 14, lines 15-46) in current claims 14-18. The method steps of '524 are the same as the instant claims. Kais discloses administration of docusate metals to human patients, which are the same

population as those instantly claimed. '524 discloses the use of docusate metals in the same dosing range as the instant claims. Relieving constipation induces at least a degree of fed mode within the scope of the instant claims. Since, '524 meets all elements of the instant claims, his method also inherently anticipates the intended use of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

IV. Claims 1-9, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/47285 ('285) taken with MacKenizie et al., Fundamental and Applied toxicology.

'285 is directed to a solid matrix pharmaceutical composition in the instant claim 1 (see page 3, lines 3-13). The fed mode (i.e., oral administration) inducing agent is retained in the solid matrix (current claim 2) (see page 3 lines 20-23). Immediate release of the fed mode reducing agent upon contact with gastric fluid (current claim 3) (see page 3 lines 32+) occurs; and, the size of the solid matrix prior to ingestion is sufficiently large to promote retention in the stomach as in current claim 5 (see page 3 lines 23-26). The composition swells and expands upon contact with gastric fluid as in current claim 6 (at page 3 lines 9-11); and, in current claims 8 and 9 the fed mode inducing agent is from 50mg-200mg (at page 6 lines 29-34).

MacKenzie et al., teach reduction of body weight/mass in individuals receiving the instant active agents (alkali and alkaline earth metal docusates) in claims 1 and 14-18. (See abstract). The instant claims require administration of specific levels of active ingredient (see page 54 left column second ¶ underlined section, and also at page 54 right hand col. under diet preparation underlined). MacKenize teach active agent at 0.1, 0.5 or 1.0 %, calculated to be 1000 mg as the purity of the active metal docusate is 99.4% (see section Methods) and meets the limitation of the instant claims 8 and 9.

Claims 1-9, 14-18 differ from the above cited prior art by reciting the pharmaceutical composition (current claim 4) wherein the fed mode inducing agent is separate from the solid matrix. There is no definition given for the solid matrix.

However it would have been obvious to one of ordinary skill in the art at the time of the claimed subject matter to administer the fed mode-inducing agent separately from the solid matrix, because one of ordinary skill would have the reasonable expectation of

success. (see the MacKenize reference where the animals where fed with the claimed metal docusates). With regards to the dosage, the determination of dosages having the optimum therapeutic index is well within the ordinary skill in the art and the artisan would be motivated to determine the optimum amounts to get the maximum effect of the drug.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

V. Claims 23-26, 47-48, 97-110, 116-120, 123-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/47285 ('285) taken with WO 98/247502 ('502) and MacKenizie et al., Fundamental and Applied toxicology, further in view of Hagen et al., PNAS, Shaffer et al., American Society of clinical Nutrition and Pupovac et al., J. Nutrition

The '285 and '502 references and MacKenzie et al. are applied here as indicated in the preceeding rejection.

One of ordinary skill in the art would have combined the Hagen et al. reference which teaches administration α-lipoic acid to mammals as a satiety composition recited in instant claims 23-24 and 123-124 because α-lipoic acid has been used in the past in satiety composition.

One of ordinary skill in the art would have combined the Shaffer et al. which is directed to the effects of xylitol (sugar alcohol) calorie intake on gastric emptying, (see abstract). Thereby meeting the limitations of claims 112-115.

One of ordinary skill in the art would have combined the Pupovac et al. which teaches β-casomorphin affect food intake is by delay of gastric emptying, an obvious variation to claims 19-20, and 121-122 because the combination of these drugs (β-casomorphin and xylitol) with that of '502 and '285 would have resulted in promoting the the fed mode of the patient in need thereof as both compounds/drugs have been used as to promote satiety.

The claims differ in that the '502 reference teaches the use of a thio-organic acid, but not the recited dithio-organic acid, nor the fed mode inducing agent acesulfame. However, it would have been obvious to one of ordinary skill in the art at the time of the claimed subject matter to select a dithio- organic compound (α-lipoic acid) because an ordinary artisan would have reasonable expectation that using α-lipoic acid, would work as it has been used successfully in the past as a satiety composition and it is well known dithio-organic compound in the art. With regards to the dosage, the determination of dosages having the optimum therapeutic index is well within the ordinary skill in the art and the artisan would be motivated to determine the optimum amounts to get the maximum effect of the drug.

Thus, the combined the teachings of '285 '502, MacKenzie, with each of Hagen et al, Shaffer et al, and Pupovac et al. result in adding add xylitol, β-casomorphin and α-lipoic acid to the composition as these compounds are well known in the art to maintain satiety in order to increase the fed mode duration (see Shaffer et al page 746 discussion section).

VI. Claims 105, 125-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/47285 ('285) taken with Yaksh US 6,576,650 B1 and further in view of Theeuwes et al., also US 3,916,899.

'285 teaches the fed mode inducing agent as directed to current claims 143-151, (see sections IV and V supra). It is obvious that the fed mode inducing agent will move out of the solid matrix, absent factual evidence. When a soluble solid is placed in a liquid, the salt will slowly dissolve at a rate supported by the permeability of the coated surface, is supported by Theeuwes et al., also US 3,916,899 (see abstract)

Yaksh teaches the compound of current claims 125-126 and 128-129 (at col.13 lines 55-65). It is obvious that relieving diarrhea as taught in the reference would at least induce a degree of fed mode, within the scope of the instant claims, therefore making the teaching obvious (see col. 4 lines 47-50).

It would have been obvious to one of ordinary skill in the art to combine the '285 reference with that of Yaksh, add the compounds of Yaksh to '285 at the time the claimed invention was made because, the compound of Yaksh is an anti diarrhea compound. (i.e., the fed mode inducing agent will have a longer duration in the stomach).

One of ordinary skill in the art would have been motivated to combine the above teachings and expect a successful result in doing so, since the compounds of Yaksh are known anti-diarrhea compounds.

Therefore administering a solid matrix comprising the aforementioned compounds/agents together with the compound of Yaksh would help the patient with diarrhea problem and increase the fed mode condition.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

VII. Claims 1, 32-34 and 130-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/47285 ('285) taken with WO 98/247502 ('502) and MacKenizie et al., Fundamental and Applied toxicology, Hagen et al., PNAS, Shaffer et al., American Society of clinical Nutrition and Pupovac et al., J. Nutrition

With regards to the above-mentioned claims, the reference teaches administering peptides and proteins that are labile upon exposure to gastric pH or gastric enzymes (see page 7 lines 25-30) directed to claims 32-34 and 130-133. It would have been obvious to one of ordinary skill in the art to choose the dipetides of the claimed invention because dipeptide drug protects the undissolved drugs from dissolving until it gets into the gastrointestinal track and react with the gastric acid (see page 7 lines 25-37).

The reference also teaches, administering drugs (anti bacteria/antimicrobial) to eradicate *Helicobacter pylori* from the gastrointestinal tract (GI) (at page 7 lines 10-20). It would have been obvious for the skilled artisan to add an alkyl pyridinium halide; noting related compounds of such would be expected to share common properties.

With regards to the amount "effective amount" it is within the skill of the artisan to optimize the doses for maximum effectiveness, which is a normal activity in developing a regimen for its use.

One skilled in the art would be motivated to employ the teachings of '285 and combine it with the aforementioned references, since the composition of such a drug would be useful in providing satiety, relieve diarrhea, promote a healthy GI, and overall health of the individual in need thereof.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
11/29/05

DWAYNE JONES
PRIMARY EXAMINER